THE POLICY FOLLOWS:
A NEW THEORY FOR DEVELOPING A VALUE-BASED, POST- PANDEMIC HEALTH CARE SYSTEM IN THE UNITED STATES

by
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Abstract

Health care policymaking, particularly as it relates to technology and innovation, is extraordinarily complex and often fraught with unforeseen consequences. This thesis explores the intricate political history and economic underpinnings of the American health care system, which have created the most expensive, and many would argue—most inefficient—system in the world. More specifically, it examines the impact of technology and innovation on the evolution of that system. The *Policy Follows* approach to health care policymaking introduced in this thesis, provides a clear and forward-thinking approach to integrating research, evidence, and expertise into the creation of informed and impactful health policy. Recent, relevant case studies illustrate the pitfalls of aggressive or poorly-informed health care technology policies advanced by political or industry agendas without the guidance of adequate scientific support. I examine the impact of the COVID-19 pandemic on the health technology landscape, with particular attention to the precipitous expansion of telehealth and virtual care services as a means of addressing the associated challenges, and discuss the imminent policy and regulatory questions facing the health care system as it emerges from this unprecedented national state of emergency. Prior to the pandemic, the growth and adoption of telehealth across the country was greatly inhibited by a several key barriers, particularly state-by-state variation in policies, the conflicting incentives of a fee-for-service based system, and an overall lack of rigorous research to guide development. The *Policy Follows* approach elucidates the path forward, guided by research and expertise, to developing evidence-based health technology policies that will facilitate the

post-pandemic transformation of health care in the U.S. into a more equitable, efficient, cost-effective, and integrated system.

Primary Reader: Marilyn Serafini

Secondary Reader: Jason Linde

Dedication

This thesis is dedicated to my mother, who has passed along her love of learning and somehow managed to teach me twelve years of economics in four months. And to my father, who has spent a lifetime teaching me the skill of meaningful communication and the art of balancing it with intuition and empathy.

And to my husband, who knows why.

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In addition, I wish to express gratitude to my colleagues and mentors; Mr. Tom Leary, Dr. Alison Curfman, Dr. Christina Olson, Dr. John Chou, Dr. Sonja Ziniel, Mr. Michael Manley, Mr. David Gray, Ms. Maggie Cash, Ms. Molly Valerio, and Dr. David McSwain, who have all provided critical insights, professional, and personal support throughout this process.

Contents

Introduction

President Donald Trump once infamously stated that health care "is an unbelievably complex subject. Nobody knew health care could be so complicated." In truth all policymaking is difficult, particularly in the United States, where lawmaking is subject to the unique and complex intricacies of our system of checks and balances. Since health care's inclusion as an important policy issue in our political platforms, it has also been subject, like most policy agendas, to the prevailing political whims and social sentiments of the day. However, what separates health care from other policy planks is that its subjugation to such whims and sentiments holds actual—and occasionally immediate—life and death consequences for our citizens.

These consequences have become even more pronounced in an era marked by increasing globalization, political polarization, and the most rapid evolution of innovation the world has yet seen. And it has not escaped anyone's attention that, while the US spends more money on health care than any other nation in the world, we often do not get what we pay for. In 2018 a joint study between Harvard's TH Chan's School of Public Health and The London School of Economics, published in the Journal of the American Medical Association, confirmed this, "in 2016, the U.S. spent 17.8 percent of its gross domestic product on health care, while other countries ranged from 9.6 percent (Australia) to 12.4 percent (Switzerland). Life expectancy in the U.S. was the lowest of all 11 countries in the study, at 78.8 years; the range for other countries was 80.7 to 83.9 years."[1] This is particularly true given that the US is also a world leader in health

[1] K. Feldscher. March 2018. "What's Behind High US Health Care Costs?" *The Harvard Gazette.*

care technologies. Should innovation not improve outcomes and lessen the expense of care? It should. The perennial debate is over why it has not.

This thesis establishes a clear and forward-thinking approach to the development of health care policy, specifically as it relates to new technologies, an approach I term *policy follows*. I provide the historical context of health policymaking, the economic and political underpinnings of today's health care system, and case studies of failed policy implementation, to illustrate the importance of the *policy follows* methodology. Finally, I use the pandemic as a laboratory for examining the strengths and weaknesses of our policymaking decisions to date and provide recommendations for how the *policy follows* method might best be utilized to assist in the development of a new, post-pandemic care delivery system.

CHAPTER 1 – Why is the Provision and Policymaking of Health Care so Difficult?

INTRODUCTION

"There is nothing more fraught than health care, because it is so personal and it is so intimate, and every political party that decides to take on health care in some massive, poorly-understood way reaps both the backlash and political retaliation."

> - *Charlie Sykes, conservative political commentator, on PBS Frontline, "America's Great Divide: From Obama to Trump."*

Health care is complicated. This is rarely more evident than in the field of health care policymaking. Indeed, both the Executive branch and Congress have labored over passing comprehensive health care reforms since the rise of progressivism and the administration of Theodore Roosevelt.[2] Republican and Democrat lawmakers alike have tried and failed. In fact, the United States does not currently crack the top ten of the nations with the best access to health care in recent surveys.[3] A 2019 World Health Organization special study ranked the US as 37th in the world for nations with the best health care systems.[4] This chapter delineates the historical context of the current U.S. health care system, explicates how the introduction and rapid pace of accelerated

[2] L. Manchikanti, S Li Helm, RM Benyamin, JA Hirsch. 2017. "Evolution of US Health Care Reform." *Pain Physician* 3 (20): 107-110.
[3] B. Sawyer, D. McDermott. 2019. "How does the quality of the US healthcare system compare to other countries?" *Peterson Kaiser Health System Tracker.* March 28. Accessed May 2019. https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/#item-percent-used-emergency-department-for-condition-that-could-have-been-treated-by-a-regular-doctor-2016.
[4] A. Tanden, et. al., "Measuring Overall Health Performance for 191 Countries." 2019. *World Health Organization.*

health information technology (HIT) has complicated the process of policymaking, and introduces the two arguments most often employed by those who seek to set and inform the agenda for HIT policy, the philosophies of *policy leads and policy follows.* My thesis is that the *policy follows* approach is the sounder methodology for creating efficacious policies designed to support a health care system that can respond effectively to the rapid and often tumultuous advancements in health care technology.

HISTORICAL CONTEXT

The Rise of Hospitals as the Center of the Health Care Ecosystem: An Early Example of the Policy Follows Approach Driven by Health Care Technology

Hospitals exist as we know them today largely due to the evolution of technology in health care, and this history underpins much of our current debate around health care policy. The earliest practice of hospital care—or the closest approximation thereof—was the medical care provided in almshouses or institutions dedicated to housing and caring for the homeless and indigent, in the mid 1700s.[5] The first facility in the colonies to focus primarily on treating medical conditions, the Pennsylvania Hospital, was founded by Benjamin Franklin in 1751. These early hospitals served mainly the poor and were funded almost entirely by individual donations and philanthropic organizations. The middle class and affluent generally received medical care at home, and paid set, and relatively modest, fees for care directly to the physician.[6] Public hospitals in the U.S.

[5] Wall, Barbara Mann. "History of Hospitals". University of Pennsylvania Nursing.
[6] Moseley, George B. "The U.S. Health Care Non-System, 1908-2008". *American Medical Association, Journal of Ethics.*

began to proliferate between 1860 and 1930, a rise that can be directly tied to the precipitous increases in technological innovation during the Industrial Revolution, as these facilities allowed for the provision of more advanced care than could reasonably be administered at home. [7] Providing one of the earliest examples for the success of the *policy follows* approach, scientific advancements, improvements in medical education and licensure standards, alongside new guidelines for hospital organizational structures and management between 1900 and 1920, led to significant increases in physician status and income and an increasing acknowledgement of hospitals as credible sites of care across all socio-economic strata.

The *Almost* Rise of National Health Insurance in the U.S.: When Policy Doesn't Follow Evidence and the Experts

Not coincidentally, the early 1900s also marks the beginning of the contentious debate surrounding the U.S. health care system. While this period would see the emergence of some form of national health insurance systems, or social insurance, in numerous European nations—most notably Germany in 1883—the U.S. did not follow suit.

The political motivations for the early European movement toward providing social insurance are important to consider. They were not meant to address a perceived fundamental right to health care and were not backed by socialist or labor parties. Instead, these programs, supported by conservative government, were intended to

[7] Melin, David Maxwell. "The Industrial Revolution and the Advent of Modern Surgery." *Intersect.* 2016.

stabilize incomes by decreasing the economic risk of lost earnings due to illness or injury, which were becoming increasingly ubiquitous during the industrial age. European programs did not initially cover the entirety of the population and were leveraged to gain political allegiance from the working class.[8] Yet, despite the European movement, by 1908 physicians and hospitals in the U.S. remained largely unregulated, and health policies were not offered by insurance companies.

The unsuccessful U.S. campaign for social insurance was spearheaded by the Socialist Party in the early 1900s and was added as a plank in the Progressive Party's platform when Theodore Roosevelt introduced the party before the 1912 presidential election. The strongest organizational advocate for nationalized social insurance was the American Association of Labor Legislation (AALL), founded in 1906, which consisted loosely of a coalition of academics and experts, "actuaries, lawyers, social scientists, and economists"[9]—the very experts this thesis maintains should have a strong voice in policy development. The AALL was primarily devoted to writing and promoting legislation defending fair workmen's compensation and demanding employers' coverage of medical care for industrial work accidents and related diseases. In 1912, while the federal debate begun under Roosevelt's term continued, the AALL drafted state-focused legislation similar to the United Kingdom's National Health Insurance law, passed the year before. In 1915, they again drafted state-focused legislation, this time mirroring Germany's income-based approach to coverage. But the attempts to introduce

[8] Van Langendonck, Jozef. "The European Experience in Social Health Insurance." Social Security Administration, Social Security Bulletin. 1973.
[9] Smith, J.P. "The Politics of American health care." *Journal of Advanced Nursing.* 1990. 15, 487-497.

such bills at the state level failed in the face of stalwart opposition by numerous influential groups with wide-ranging interests, including the American Medical Association, large insurance companies, the Christian Science Organization, the vast majority of employers, and the American Federation of Labor (AFL), the largest union group in the U.S. for the first part of the 20th Century. Further, in stark contrast to Europe, a strong working-class voice for national social insurance was largely absent.[10]

The 1920s saw an increase in hospital use and costs as the number of middle-class workers who sought care outside of the home began to rise. In 1929, the first pre-paid service plan for a group of employees to receive a predetermined amount of care with a local hospital, and similar plans with larger groups of hospitals, became increasingly popular during the height of the Great Depression. These arrangements, which expanded rapidly, were soon consolidated becoming known as the Blue Cross network and were heralded as a symbiotic relationship allowing workers to receive care at a decreased cost while assuring the financial viability of floundering hospitals.

In 1926, the Committee on the Cost of Medical Care (CCMC) was convened by eight of the largest philanthropic funders of hospitals, to study the growing public need for health care. The committee, like the AALL, consisted of experts representing the fields of economics, medicine, and public health, and included representatives from the most powerful interest groups of the period. The CCMC was prolific, turning out scientific research resulting in twenty-six volumes and a few, more specific, reports over the span

[10] Palmer, Karen S. A Brief History: Universal Health Care Efforts on the US. 1999. Physicians for a National Health Program.

of five years. Their research findings revealed a significant increase in health care consumption, identified new and emerging trends in types of health provision, suggested the need for preventative care through community-based or public health centers, and called for an increase in national spending to cover the growing needs of the country—particularly those without any access to care. The committee also recommended a national health insurance program. Though they did not specify whether this program should be voluntary or compulsory, they did stipulate that funding should be provided through taxation. This evidence-based focus on preventative, population-based health care services over the more specialized and reactive, fee-for-service model foreshadowed the future development of, and intense debate over value-based care models in the U.S., and is a pivotal moment in what will become the U.S. trend toward a *policy leads* approach in health care, so often associated with big business and powerful special interest groups.

The CCMC's efforts quickly drew the ire of the AMA, which in 1933, published an editorial in their academic journal characterizing the report as "an incitement to revolution, socialist, and communist" [11] The AMA staunchly opposed any additional government spending or involvement in health care, primarily based not on scientific evidence, but on concerns that the growing number of health plan agreements would limit physician income, which was based on a fee-for-service model. This focus on the preservation of fee-for-service payments to physicians led to the establishment of a

[11] Gore, Thomas. "A forgotten landmark medical study from 1932 by the Committee on Cost of Medical Care." *Baylor University Medical Center Proceedings.* 2013.

physician-backed network of plans designed to cover their own primary care services, later to become known as Blue Shield.[12]

President Franklin Roosevelt, already well underway with the “first hundred days” of his social programs known collectively as the New Deal, was too busy attempting to pull the nation out of the depths of the Great Depression to pay heed to the debate over social insurance. However, by 1934 FDR had appointed an Economic Security Committee (ESC) and had already begun considering serious measures to overhaul federal safety net programs for workers, including social security and proposals on national health insurance models. Debates from within the ESC medical advisory committee were heated, as some physicians backed the AMA’s oppositional position while others warned that history would condemn the medical community for not supporting inclusion of health insurance in the social security legislation. In 1935, the Social Security Act was passed without inclusion of a health insurance plan. While this was a politically well-calculated move, the failure to enact early evidence-based policy set into motion an accumulation of government responses that would eventually lead to the development of the world’s most expensive, complicated, and unequitable health care system.

[12] Moseley, George B. “The U.S. Health Care Non-System, 1908-2008.” *American Medical Association, Journal of Ethics*. 2008.

Employer-Based Health Insurance Coverage: A Uniquely American, and Problematic, Early Example of Policy Leads

In 1941, the U.S. entered World War II and with many of its citizens deployed overseas, the nation faced a labor shortage. In 1942, concerns over rampant inflation led to passage of the Stabilization Act, which froze wages by barring employers from raising pay to compete for workers. To counter, businesses began offering health care "benefits," like the service plans that led to the creation of the Blue Cross and Blue Shield plans in the previous decade. In 1943, the Internal Revenue Service authorized tax exemption status for employer-based health insurance. [13] This, in combination with the rise of hospital and physician-focused insurance programs, began what has become the problematic link between the health care system and employer-based health insurance.

Over the next several decades hospital-based care increasingly became the focus for private and public payments strategies, as well as for providers. Significant advancements in medical technologies in the 1950s and 1960s, the continued expansion of the number of insured workers, and President Johnson's passage of amendments to the Social Security Act, increased the cost of health care and the complexity of the American health care system exponentially. [14]

[13] Thomasson, Melissa. *From Sickness to Health: The Twentieth-Century Development of U.S. Health Insurance.* Explorations in Economic History. July 2002. Vol. 39 (3). Pgs. 233-253. doi:10.1006/exeh.2002.0788.
[14] Berkowitz, Edward. "Medicare and Medicaid: The Past as Prologue." *Health Care Finance Review*. Winter, 2005.

THE DIGITIZATION OF HEALTH CARE

"I know there's a proverb which says, 'To err is human,' but a human error is nothing compared to what a computer can do if it tries."

- Agatha Christie, *Hallowe'en Party*

The complexity of the American health care system has grown substantially in the era of health information technology (IT). Beginning with the rise of personal computing in the 1970s and 1980s, through the advent of the internet in the 1990s, the rapid adoption of electronic health records in the 2000s, and the surge of big data and analytics in the 2010s and beyond, health IT has rapidly become the driving force behind health care innovation. Health IT now includes a broad array of technologies deployed throughout every function of the health care system, including clinical, operational, compliance, billing, and finance. These technologies include electronic health records, communications systems, patient monitoring, imaging, laboratory systems, and telehealth, to name a few. Adding to the complexity of health IT is that all of these areas are tightly interwoven. Therefore, any policy or regulatory change implemented within the health care system will inherently have broad implications not only for the area targeted by the policy or regulation, but for multiple other areas as well.[15] Unanticipated consequences are the norm, and a multitude of administrative and

[15] "Electronic Health Records; Patient Safety Primer". *Agency for Healthcare Research and Quality*. PSNet. Last updated January 2019. https://psnet.ahrq.gov/primers/primer/43/Electronic-Health-Records

technical processes in the health IT management of a health care organization are focused on how to respond to unanticipated effects of change.[16]

Health care is not the only, and certainly not the first, industry to contend with the complexities and pressures of integrating technology into established practice. The business world has been adapting to rapid advancements in technology which have spurred inclinations toward globalization and shifting economic markets since the rise of the knowledge economy in the post-industrial era.[17] These changes have caused companies to expand their teams to deal with a growing number of external business partners and challenged the ability of corporations to limit its physical presence to a specific geographic location. To accommodate these changes businesses have adopted the practice of video-conferencing technologies, to allow for a virtual "face to face" meeting for team members in multiple locations.[18] Over the last two decades this practice has led to the creation of a multi-billion-dollar industry focused on video conferencing platforms and their use in other fields such as education and personal communication.

The banking sector is another industry which has been significantly impacted by technology. Widely available network connectivity, cybersecurity protocols, online banking and mobile technology have driven banks to leverage these innovations to

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[16] "Guide to Reducing Unintended Consequences of Electronic Health records." *The Office of the National Coordinator.* HealthIT.gov. 2019. https://www.healthit.gov/unintended-consequences/

[17] World Bank Group. The Knowledge Economy and the Changing Needs of the Labor Market. http://siteresources.worldbank.org/INTLL/Resources/Lifelong-Learning-in-the-Global-Knowledge-Economy/chapter1.pdf

[18] Jon Martin Denstadli, Tom Erik Julsrud, and Randi Johanne Hjorthol. 2012. "Videoconferencing as a Mode of Communication: A Comparative Study of the Use of Videoconferencing and Face-to-Face Meetings." *Journal of Technical and Business Communication.* 1 (26): 65-91.

revolutionize the means by which consumers and businesses interact with financial institutions. In 2017, 1.51 billion mobile devices were sold in the United States, with global expansion of the market exceeding the rate in the U.S.[19] With 96% of all Americans having access to mobile technology,[20] the ways in which all markets are approaching provision of their services has changed. The health care industry is no different. Between 2011 and 2012, the number of mobile device users who downloaded at least one mobile health application onto their device doubled.[21] The increasing consumer demand for added value in health care and disruptions caused by these emerging innovations has spurred the health industry to also reassess the manner in which it provides care to patients. With the U.S. experiencing trends such as an aging population, increases in chronic disease rates,[22] increased health care disparities between differing ethnic groups and between rural and urban populations,[23] and skyrocketing health care costs, the expansion of technologies to address these issues is increasingly key. However, the adoption of information technology and advanced telecommunication into health care has lagged other industries. In fact, many health care institutions still rely heavily on pagers, paper records, and fax machines, despite the explosion of video communication, big data and analytics and digital information exchange in other sectors. [24] This is due in part to the size and complexity of the

[19] Andy Boxall. 2019. "In 2018, smartphone sales stopped growing annually for the first time." *Digital Trends*. https://www.digitaltrends.com/mobile/2018-smartphone-sales-decline-news/
[20] Pew Research Center: Internet and Technology. Last updated June 12, 2019. https://www.pewinternet.org/fact-sheet/mobile/
[21] S. Wilson, Open Mobile: The Growth Era Accelerates. The Deloitte Open Mobile Survey 2012, 2012, Deloitte Research. http://www.deloitte.com/view/en_US/us/Industries/Telecom-Telecommunications-Technology/69f289e50b484310VgnVCM2000001b56f00aRCRD. htm.
[22] https://www.ncbi.nlm.nih.gov/pubmed/12645839
[23] Kendal Orgera and Smantha Artiga. 2018. "Disparities in Health and Health Care: Five Key Questions and Answers." *Kaiser Family Foundation*. https://www.kff.org/disparities-policy/issue-brief/disparities-in-health-and-health-care-five-key-questions-and-answers/
[24] Sarah Kliff. 2018. "The Fax of Life: Why American Medicine Still Runs on Fax Machines." *Vox.* https://www.vox.com/health-care/2017/10/30/16228054/american-medical-system-fax-machines-why

industry but is significantly complicated by the sensitivity and intense regulation around patient data, as well as concerns for patient safety.

In such an unpredictable and complex environment, a high level of expertise is required to inform meaningful policy and regulatory changes. Effective health IT policy development often requires extensive involvement by experts in clinical care, data science, informatics, finance, epidemiology, operations, and business, not to mention the obvious required expertise in legislative process and in the relevant technology. The variety of clinical disciplines and wide array of technologies utilized in health care further expands the field of required expertise.

Of course, the more experts that become involved in the legislative process, the greater the potential for differences of opinion, particularly when various experts are approaching a problem from a different silo of expertise. The business solutions to health care's problems, as determined by experts in health care finance and management, for example, do not always align with the optimal clinical solutions or ideal technical solutions, as determined by experts in those areas. Thus, the difficulty of developing well-informed and impactful health care IT policies is compounded further.

This is perhaps best exemplified by the federal policy and regulation surrounding Electronic Health Records (EHR), which were originally conceived as a means of decreasing medical errors, improving patient care, and increasing provider efficiency. The promise of EHRs was recognized by the Obama administration, and incentives for

adoption of EHRs were incorporated into the language of the American Reinvestment and Recovery Act (ARRA), in 2009.[25] However, implementation of EHRs across the country was slow and inconsistent, and while additional regulations imposed on health care systems around EHRs in the 2015 Medicare Access and CHIP Reauthorization Act (MACRA) accelerated the pace of implementation, it did not improve the EHR's effectiveness at addressing the problems it was originally meant to address.[26] In addition, industry factors led to persistent problems with information blocking and a lack of interoperability by competing EHR vendors. All this has largely influenced the current health care landscape, where much of the blame for the epidemic of physician burnout and continuously increasing costs is placed on the very technology that was conceived as a solution to these issues.

With even more new and emerging technologies such as telehealth, (an example this thesis will continue to highlight given its enormous growth and impact during the COVID Pandemic response), remote patient monitoring, wearable devices, artificial intelligence, machine learning, and advanced analytics, this wide array of expertise must also be supplemented by academic research into the implementation and impact of these technologies. Unlike other technology sectors, the requirement of rigorous scientific evidence to inform practice change is deeply ingrained into the health care system, and for good reason. Unanticipated effects and ineffective solutions in health care have life and death consequences, and an immense research infrastructure has developed

[25] Taylor Burke. 2010. "The Health Information Technology Provisions in the American Recovery and Reinvestment Act of 2009: Implications for Public Health Policy and Practice." *Public Health Reports.* Jan-Feb; 125(1): 141–145. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2789830/
[26] Peter Basch, Thomson Kuhn. 2016. "It's Time to Fix Meaningful Use." *Health Affairs.* January 14. https://www.healthaffairs.org/do/10.1377/hblog20160114.052678/full/

around and within health care to minimize such negative impacts. Still, the pace of technology development is often at odds with the need for rigorous clinical and translational research, leading to a chaotic environment that has seen more than its fair share of dramatic standoffs and failures.

THE POLICY LEADS VS. POLICY FOLLOWS ARGUMENTS

Telehealth is the use of electronic communications, including real-time audio-video, remote monitoring, e-consenting, and other approaches, in the delivery of health care services. Telehealth has vast potential to address the Institute for Health care Improvement's (IHI), Quadruple Aim for Health Systems: improving the health of populations, reducing per-capita costs, improving the patient experience of care, and improving the work-lives of health care providers.[27] [28] [29] [30] [31] [32] [33] [34]

[27] S. Al Kasab, J. B. Harvey, E. Debenham, D. J. Jones, N. Turner, and C. A. Holmstedt. . 2018 "Door to Needle Time over Telestroke-A Comprehensive Stroke Center Experience." *Telemed J E Health* 24 (2):111-115. doi: 10.1089/tmj.2017.0067.

[28] M. Barnett. L., H. F. Yee, A. Mehrotra, and P. Giboney. 2017. "Los Angeles Safety-Net Program eConsult System Was Rapidly Adopted And Decreased Wait Times To See Specialists." *Health Aff (Millwood)* 36 (3):492-499. doi: 10.1377/hlthaff.2016.1283

[29] M. Becevic, S. Boren, R. Mutrux, Z. Shah, and S. Banerjee. 2015. "User Satisfaction With Telehealth: Study of Patients, Providers, and Coordinators." *Health Care Manag (Frederick)* 34 (4):337-49. doi: 10.1097/HCM.0000000000000081

[30] M. E. Davalos, M. T. French, A. E. Burdick, and S. C. Simmons. 2009. "Economic evaluation of telemedicine: review of the literature and research guidelines for benefit-cost analysis." *Telemedicine journal and e-health : the official journal of the American Telemedicine Association* 15 (10):933-948. doi: 10.1089/tmj.2009.0067 [doi]

[31] M. Dharmar, P. S. Romano, N. Kuppermann, T. S. Nesbitt, S. L. Cole, E. R. Andrada, D. Vance, Jillian Harvey, and James P. Marcin. 2013. "Impact of critical care telemedicine consultations on children in rural emergency departments." *Critical Care Medicine* 41 (10):2388-2395. doi: 10.1097/CCM.0b013e31828e9824 [doi]

[32] James P. Marcin. 2013. "Telemedicine in the pediatric intensive care unit." *Pediatric clinics of North America* 60 (3):581-592. doi: 10.1016/j.pcl.2013.02.002 [doi]

[33] B. Odeh, R. Kayyali, S. Nabhani-Gebara, N. Philip, P. Robinson, and C. R. Wallace. 2015. "Evaluation of a Telehealth Service for COPD and HF patients: Clinical outcome and patients' perceptions." *J Telemed Telecare* 21 (5):292-7. doi: 10.1177/1357633X15574807

[34] R. E. Powell, J. M. Henstenburg, G. Cooper, J. E. Hollander, and K. L. Rising. 2017. "Patient Perceptions of Telehealth Primary Care Video Visits." *Ann Fam Med* 15 (3):225-229. doi: 10.1370/afm.2095

The early advancement of telehealth has been driven more by theoretical impact than by rigorous research and development of best practices. Additionally, state-to-state variation in regulations, reimbursement, and wide discrepancies in resources result in great variability across institutions in telehealth practice and provision of services.[35] Just as existing telehealth policies and regulations are not fully developed, there are generally two well accepted but not necessarily well-defined arguments regarding how to best approach fostering sound telehealth legislation and regulation.

The *Policy Leads* Argument

It is a widely-held belief among many in the telehealth industry that rigorous academic telehealth research is both unnecessary to the advancement of telehealth services and prohibitively slow. The thought is that the development and large-scale adoption of telehealth services should be driven largely by innovation and consumer-focused competitive factors such as improved convenience for patients and efficiency or income for providers. This school of thought views telehealth under much the same lens as one might view Netflix, Amazon, or the iPhone: a new and promising technology that will ultimately reach a tipping point of adoption without waiting for academic research to catch up to evolving practice.

[35] Jillian Harvery, Shawn Valenta, Kay Simpson, Mark Lyles, and James McElligott. 2018. Utilization of outpatient telehealth services in parity and non-parity states 2010-2015. In Press *Telemedicine and e-Health*.

Policy development in this school of thought is seen as a necessary first step to hasten this advancement by lightening the regulatory burden on telehealth providers and eliminating or reducing reimbursement barriers. Academic research is not seen as a central component to this advancement but rather as a likely outcome of it.

The conduct of such high-level research requires policies and legislation to support sufficient data acquisition. According to a 2018 policy report:

> Disciplines that assess the impact of technology on institutions and enterprises encounter the same problem, as advancements in technology often outpace the production of peer-reviewed research. By the time such research is published, the technological landscape has likely changed in a way that limits practitioners' and policymakers' ability to employ its findings.[36]

In this school of thought, policy studies and industry reports are most critical to the timely progress of activities that employ advanced technologies.

From this perspective, the passage of a federal parity law and advocacy for a state-by-state, broadly framed and uniform parity law, is ideal. Once these policies push the adoption of telehealth over the critical tipping point, making telehealth practice ubiquitous across the health care service spectrum, academic research will naturally follow. The concern, however, is that a lack of academic telehealth research will both inhibit adoption by academically-minded providers and lead to the advancement of

[36] Katherine Restrepo. 2018. "Policy Report. The Case Against Telemedicine Parity Laws: Let the market thrive in America's most regulated industry." *John Locke Foundation.* January 15, 2018. https://johnlocke.org/research/telemedicine Last accessed August 25, 2019.

largely profit-driven telehealth services that prioritize return on investment over patient outcomes and population health impacts. It is not surprising then that the Congressional Budget Office (CBO) does not accept industry-driven outcomes as non-biased reporting, meriting the same weight as research conducted within the standards of contemporary academic frameworks.

The *Policy Follows* Argument

The lack of a robust evidence base supporting the impact of telehealth has substantially impaired large-scale adoption of telehealth by both providers and patients. The CBO has specifically requested that more research be conducted on the impact of telehealth on health care spending, to allow an accurate analysis of proposals to expand Medicare coverage of telehealth.[37]

The dilemma is that the growth and adoption of telehealth services is limited by the lack of evidence supporting its effectiveness, but the development of a quality telehealth evidence base is, in turn, limited by the lack of sufficient growth and adoption to have the service volume needed to conduct adequately powered, relevant and impactful

[37] Lori Housman, Zoe Williams, and Philip Ellis. 2015. "Telemedicine." Congressional Budget Office, accessed April 23, 2018. https://www.cbo.gov/publication/50680

research.[38] [39] [40] [41] [42] Thus, concerted collaborative efforts are needed to develop a research culture in telehealth, and to develop a national platform for multisite telehealth research. In order for telehealth research to advance in a timely enough fashion to keep pace with the advancements in technologies and business practices of telehealth, researchers must bring together the scientific community to promote thorough examination, identify and prioritize telehealth research needs, catalyze collaborative, multisite research studies, catalogue emerging best practices and study design methodologies, and disseminate findings and new knowledge.

It is the identification and prioritization of telehealth research needs that can be most effectively served through the simultaneous integration of health care policy evaluation and strategy. Through evaluation of existing state and federal telehealth policy, regulations, and guidelines, research can be targeted toward meaningful studies that will address the current gaps in telehealth policies and drive the development of impactful policies at the state and federal level.

A key component of this approach is the evaluation of the economic impacts of telehealth services, including health care costs, direct and downstream revenue, return on investment, and reimbursement policies. If health care cost and efficiency issues are

[38] Stephen Agboola, and Josephn Kvedar. 2016. "Telemedicine and Patient Safety." Agency for Healthcare Research and Quality (AHRQ), accessed April 23,2018. https://psnet.ahrq.gov/perspectives/perspective/206/telemedicine-and-patient-safety

[39] N. R. Armfield, S. K. Edirippulige, N. Bradford, and A. C. Smith. 2014. "Telemedicine--is the cart being put before the horse?" *Med J Aust* 200 (9):530-3

[40] M. McCartney. 2012. "Show us the evidence for telehealth." *BMJ* 344:e469

[41] S. McLean, A. Sheikh, K. Cresswell, U. Nurmatov, M. Mukherjee, A. Hemmi, and C. Pagliari. 2013. "The impact of telehealthcare on the quality and safety of care: a systematic overview." *PLoS One* 8 (8):e71238. doi: 10.1371/journal.pone.0071238

[42] Dawn Sherling, and Michael Sherling. 2017. "The Promises and Pitfalls of Telemedicine." *The American Journal of Accountable Care*

considered prospectively as research questions, designs, and data collection plans evolve, then the data gathered from those studies will be more likely to impact financial projections used in policy development and scoring, such as by the CBO. This considered, practical, and rigorous scientific approach has the greatest potential to lead to the development of the safest and most effective telehealth services. However, the rapid pace of telehealth development may inhibit a full adoption of this methodology.

WHAT IS EVIDENCE BASED MEDICINE?

Although the practice of modern medicine has long been based on clinical and basic science research, it was not until the late 1960s that increased awareness of the weakness in clinical decision making began to be scrutinized by members of the medical community who were concerned about gaps in evidence and wide variations in clinical judgment. From this began a movement to increase the awareness of these failings and apply clear evaluation of the evidence of effectiveness in the dissemination of both clinical practice guidelines and population focused policies. The term Evidence Based Medicine (EBM), was first used in 1990 by David Eddy in an article published in the Journal of the American Medical Association and a subsequent series of 28 papers describing the need for, and the process of, creating evidence-based medicine. [43]

[43] David Eddy. 1996. "Clinical Decision Making: From Theory to Practice." *A Collection of Essays from the Journal of the American Medical Association*. 1st ed. Boston, MA. London, UK Jones and Bartlett.

How does this differ from Translational Research (also called Translational Science)?

The fundamental purpose of translational science is to create a new framework for medical research, the goals of which are: to build upon previous clinical study to create broader applications of science, ensure that those applications ultimately find relevance for the public, realize common acceptance (EBM), and influence public policy decisions. Broadly, it is meant to bring basic science out of the lab and create practical advances for the good of society. In 2004, The National Institutes of Health (NIH) pioneered the concept of translational medicine and established the *Clinical and Translational Science Awards* (CTSAs), which were granted to academic medical centers around the country to create a system of collaborative hubs, working in concert to institute the aims of the NIH's purpose.[44] [45]

In 2008, the NIH further refined the framework to include four phases of translational medicine. Commonly referred to as phases *T1, T2, T3, and T4*, these stages represent the full process beginning with bench research and ending with the conversion of all the stages into evidenced based clinical application to population health-based models of care deployment and policy development. Policy work is incorporated in both the *T3* and *T4* phases, although *T4* is the space within which most traditional policy work occurs. *T4* is defined by the NIH as:

[44] Charles Vukotich. 2016. "Provacative Idea: Challenges of T3 and T4 Translational Research." *Journal of Research Practice* 12 (2)
[45] Lori Kantor. 2008. "NIH Roadmap for Medical Research." *Alcohol Research and Health* 31 (1).

Community to Public Health: T4 research evaluates the implementation and efficacy of policies and accepted medical practices, as they impact individual and public health outcomes. T4 research may include cost–benefit analysis, policy analysis, surveillance studies, and program evaluation.[46]

CONCLUSION

The pace of increasing complexity in our health care system shows no signs of slowing in the near future. Technology has historically served as a driving force in the evolution of health care, while also contributing substantially to that complexity. Identifying a clear path forward in such a challenging environment may therefore seem like an insurmountable task. But policy development guided by science and expertise, as it has in the past, can guide us forward in the future. It is not always the easiest path to take, and can often require patience, careful proactive planning, and some sacrifice of political agendas. The next chapter will delve into recent case studies of policy that has not followed research, the lessons that we can learn from those experiences, and the economic underpinnings of our health care system that create many of the unique circumstances that policymakers must navigate.

[46] Charles Vukotich. 2016. "Provacative Idea: Challenges of T3 and T4 Translational Research." *Journal of Research Practice* 12 (2).

CHAPTER 2 – Lead from Behind: Why a "Policy Follows" Approach is the Best Way to Lead Health Care Forward

INTRODUCTION

The American healthcare system has become a self-perpetuating behemoth. Incrementalist approaches to change often have limited impact. Any gains made rapidly evaporate as the system adjusts to maintain its *status quo,* like lobbing a water balloon into a raging housefire. Conversely, passage of aggressive, transformational health care legislation not only requires the expenditure of enormous political capital, but due to the unique, layered complexities of our system, the consequences of such considerable change are often difficult to predict.

Health care Information Technology (IT) is central to the operation and evolution of our health care system, but developing policies to address advancements in technology adds yet another layer of complexity to the policy-making process. Conventional wisdom in health care IT policy is that aggressive technology policies can drive innovation. Policies supporting promising new innovations by decreasing regulatory hurdles or incentivizing adoption will drive implementation of new technologies and the possible, resulting benefits to the system. But legislating within a poorly-understood health care environment risks more than political retaliation—it risks lives. And thus, gaining a deeper understanding of the basis for, and likely consequences of, policies

and regulations impacting health care IT is critical to creating successful legislation. In such a complex field, this understanding requires patience, research, and the help of experts.

In this complicated environment, how do we successfully advance effective and safe health IT policy? My thesis is that driving effective health IT policy requires that *policy follows* research and expertise—that we must prioritize evidence-based policy in the same way that health care professionals prioritize evidence-based medicine. We have seen repeatedly that, when *policy leads* in an effort to drive innovation or financial outcomes, the unforeseen consequences often greatly outweigh any achievements and in a system such as ours, such missteps can be a difficult thing from which to recover.

Policy leads is an environment wherein lawmakers and regulators put into place legislation that dictates or encourages certain behaviors by creating rules around payment and imposing penalties for non-compliance. *Policy follows*, by contrast, describes an environment where technological innovation in health care drives practice change through research and evidence, and those researchers and other experts in the field of medicine are then called upon to identify policy alternatives for legislators based on scientific evidence and data, that would further advance the broad adoption of successful practices.

This chapter's purpose is two-fold. It explores the economic and political theories, and their broadly drawn ideological counterparts, upon which the politico-economic framework of our health care system is built, and provides illustrative case studies which demonstrate the pitfalls of a *policy leads* approach to policy and regulation for health IT.

ECONOMIC AND POLITICAL THEORIES

Market Failures and Driving Innovation

The exceptional level of difficulty in creating quality and lasting health care policy and reform is in part due to the incredible complexity of the U.S. health care system itself. There are many dynamic and powerful players within the system, including consumers, care providers, hospitals and clinics, pharmaceutical companies and insurance companies, and the economic impact is immense. In 2018, the healthcare sector of our economy accounted for the nation's largest amount of spending at $3.65 trillion, up 4.6% from 2017, a rate of growth faster than that of the Gross Domestic Product (GDP) within the same year.[47] All of these variables lead to convoluted interactions between the governmental branches and regulatory agencies and fierce competition amongst interest groups for a prominent role in setting the policy agenda and guiding legislative outcomes.

In the most general terms, economic analysis of health care is complicated for two reasons. The more basic problem is that a supply and demand analysis, which should deal with delivery of service from physicians (suppliers) to patients/consumers (demanders), is distorted by the gatekeepers. Both for-profit and government insurers distort the outcomes regarding price and quantity: the price paid, and the quantity consumed. Patients cannot determine their cost of care because there are at least three payment routes. The first route is through taxes**.** A portion of our income goes to

[47] BEA. *Bureau of Economic Analysis.* April 2019.

Medicare, Medicaid, the Children's Health Insurance Plan (CHIP), and insurance marketplace subsidies mandated in the Affordable Care Act (ACA). In 2019, these four programs accounted for 1.1 trillion dollars or twenty-five percent of our nation's overall budget. The breakdown of how much of that spending goes to each program depends on numerous variables, and states must match the amount of federal payments for Medicaid and CHIP.[48] The second payment route for care is a patient's insurance premium**.** The premium amount is usually difficult to decipher and is only roughly reflected on a payroll slip listing an individual's net deposit. Insurance premiums vary widely depending on the contract between the employer and the insurance provider. The final payment route for consumers are co-pays, which also vary widely depending on the type of service rendered and the period of time during which the services are received. Possibly more surprising, is that the suppliers (physicians), also do not often know the cost of the care they provide (which determines the supply relationship), or the prices, which vary because they are determined by health system negotiations with insurers.

Secondly, health care markets actually fail for some—or many—of the defined reasons any market may fail: equity, externalities, market power, and asymmetric information. The only defined market failure that doesn't apply to health care is the public good argument.[49] This argument states that some goods are non-rival, meaning that one more person's use of the good doesn't lessen the amount available to everyone else. The prime example of a non-rival good is national defense; i.e. one person's use of the

[48] The Center on Budget and Policy Priorities. "Where Do Our Federal Tax Dollars Go?" April 2020.
[49] Henderson, James. "Health Economics and Policy: The Relevance of Economics in Health and Medical Care." 2012.

national defense does not lessen another's. Health care is a rival good, as anyone who has sat in an emergency room or waited any length of time for an appointment, can attest to. It is highly congested. Furthermore, in economic thinking, one person's medical intervention does not help another person. Here, it is important to highlight the difference between rival and non-rival goods and positive and negative externalities. An externality is a situation in which the market transaction between two parties helps (positive externality) or hurts (negative externality) a third person. The conflation between the two is often made when considering the importance of public health interventions such as vaccines. Vaccines are an example of a relatively simple market transaction between one person and a large third party, in which the good provides a positive outcome for many people. However, this describes a positive externality not a non-rival good, as the one dose of vaccine can only be used by one person.

Much of the government's promotion of health care outcomes is based on the fact that there is a strong positive externality to public health, something the CCMC's research had proven by the early 1930s. Good health benefits more than the healthy in terms of not spreading disease and in terms of strong economic outcomes. And it is worth noting that economists have often argued that medical research should also be considered a public good.[50] Yet only 2% of our annual national budget in 2019 was earmarked for science and medical research.[51]

[50] Henderson, James. "Health Economics and Policy: Analyzing Medical Care Markets". 2012.
[51] The Center on Budget and Policy Priorities. "Where Do Our Federal Tax Dollars Go?" April 2020.

In fact, the explanation for all government intervention in any sector of the economy is a market failure. A non-health care example is the case of negative externalities like pollution, for which the Environmental Protection Agency (EPA) was created. The government's reaction to mounting concerns over health care equity issues in the U.S., resulted in legislation enacting the so-called entitlement programs, including Medicare and Medicaid, CHIP, Social Security and welfare. All of which, as was described earlier, was necessarily passed in a piecemeal, *policy leads* fashion due to prevailing political agendas and strong special interest lobbies.

Another complication of our layered health care system is the power insurance companies wield in determining cost and payment. Many have argued that insurance companies tend toward monopoly power. The tendency toward monopoly is collusion, in which for-profit companies find ways to agree to provide only certain products and to do so at similar prices. In order to combat this tendency, Congress passed anti-trust laws. The extent to which insurance companies lean toward exerting a monopoly power is often debated, but clearly there are enough companies competing that anti-trust laws are not triggered.

Asymmetric information, another of the causes listed above for market failure, can be defined as "a situation in which information is unequally distributed between the individuals in a transaction." Government intervention is extremely ineffective at combating asymmetric information.[52] Unfortunately, the insurance industry suffers from this failure and combats it by attempting to limit its exposure to paying claims, hence the

[52] Jolly, BPK. "Asymmetric Information-Cause of Market Failure." *International Journal of Trends in Research and Development.*

legislative reforms of the ACA requiring coverage of those with preexisting conditions or those already too ill to work. Asymmetric information is also apparent when we again consider a supply and demand analysis in which consumers (patients) don't know the cost of a service, what options may exist, the effects of physician recommendations for treatment (or non-treatment), the role insurance companies play in the recommendations of physicians, etc.

Market Maximized versus Market Minimized: The Political Economy of Health Care

There has been a long history of aligning political parties with economic thought. In very broad terms, those who believe markets should control most of our economic choices can be labeled market maximizers. These subscribers tend to have certain political casts and may be labeled neo-liberal. Advocates of this theory downplay the role and effect of market failures in most situations and generally indicate that they feel that government intervention intended to right market failures limits the free will, both of the consumers on the demand side and the providers on the supply side. Conservative thinkers may argue that there are indeed market failures, but that government intervention does more harm than good. [53]

On the other side of the political and economic aisle are the progressive voices, who espouse that failures of the market are real and that government intervention is often the only solution—even if not the perfect one—because private companies involved in

[53] Friedman, Milton. *Capitalism and Freedom.*

the pursuit of profit are not often motivated to care for equity, or the benefits of positive externalities, or the costs of negative externalities. For the sake of rhetorical and ideological symmetry these advocates may be referred to as market minimizers. However, in reality, they do not argue for government intervention in more than a handful of markets.[54]

One of the relevant arguments in light of these views involves how the market is related to innovation. Those who advocate for maximized markets often claim that the race for profits spurs innovation. A company spends large sums to develop a new technology, or a new drug, for example, in the hope of making significant profits if its research pays off. Market maximizers would argue that a firm deprived of its profits by the government will not bother to innovate nor to improve efficiency. This may be true. It does not prohibit another group, independent researchers at universities, for example, from conducting research on innovative new products. Nor does it prohibit regulators from promoting efficiency. It does, however, remove some profit motives.

Consider another supply and demand illustration, this time for health care technology. Its product is different from the supply and demand described above. The product analyzed above is for a health care outcome, say an hour of service, regardless of the outcome—health care is the product. For the health care technology analysis, the product is something that supposedly increases efficiency, for example telehealth. This evaluation presents fewer problems in and of itself because it is now clear who the providers are and who the demanders are—health care providers are now on the

[54] Krugman, Paul. *The Conscience of a Liberal.*

demand side of the equation. Still, externality and equity issues remain and government must step in to remedy these concerns.

Yet it is clear that government involvement can backfire, and I believe the reason is twofold. First, is the lack of clarity, to even the most engaged and educated on the subject. If, for argument's sake, both sides of the body politic could come to some agreement of market failures, policymakers could have a much clearer conversation about when government intervention is needed and what it is likely to achieve. The other concern is that the original health care supply and demand analysis, the one focusing on care, is so convoluted at this point, that this more limited consideration becomes convoluted as well, and we find ourselves back at the beginning of the endless game of the partisan political economy versus evidence based policy.

One plausible way to begin to simplify the approach to legislating the health care technology market is to ensure that the innovations that government promotes into the health care market are based on rigorous, academic research. We require solidity in a sea of regulations, the necessary ones and the unnecessary. From this perspective, the *policy follows* research approach, in some ways becomes the equivalent of a profit motive. *Policy follows* provides a sound rationale for government support of evidenced based health care innovation as opposed to clumsy political attempts to enforce new technology standards that merely seem like good ideas. The following case studies provide notable examples of failed government attempts to guide innovation in health care by a *policy leads* approach and highlights the importance of the adoption of a *policy follows* standard.

CASE STUDIES

The complexity of the U.S. health care system has grown substantially in the era of health care information technology. Health care information technology (IT) includes a broad array of technologies deployed throughout every function of the health care system, including clinical, operational, compliance, billing, and finance. These technologies include electronic health records, communications systems, patient monitoring, imaging, laboratory systems, and telehealth, to name a few. Adding to the complexity of health IT is that all of these areas are tightly interwoven. Therefore, any policy or regulatory change implemented within the health care system will inherently have broad implications not only for the area targeted by the policy or regulation, but for multiple other areas as well. Unanticipated consequences are the norm, and when *policy leads,* without a strong basis in evidence and the adequate guidance from health care and research experts, those unanticipated consequences can have long-lasting and far-reaching negative impacts on the system.

Integration of research into the development of health information technology policy and regulation, the *policy follows* approach, is critical to minimize unforeseen negative impacts. According to John Kingdon's seminal work on roles played by non-governmental groups in policymaking, academics do not have as much influence as interest groups over the formation of an agenda, but they do tend to be the experts legislators rely on most for identifying alternatives to existing problems within a given agenda or policy, and they may influence the prevailing themes of scientific focus.[55] In

[55] Kingdon, John. "Agendas, Alternatives, and Public Policies." 2011.

short, academics generate the established wisdom surrounding policy problems which often informs the way policymakers approach the writing of legislation. A *policy follows* approach dictates that this influence must be even more powerful in the health care sector, as even prevailing schools of thought acknowledge that health care provision cannot be treated as a traditional producer-consumer interaction.

Case Study 1: The Unexpected Consequences of the Electronic Health Record: Good Intentions Still Require Good Data

One of the most prominent examples of this complexity and failure of the *policy leads* approach is the federal policy and regulation surrounding Electronic Health Records (EHR), which demonstrates that even the best innovations can exacerbate problems in health care when pushed forward aggressively by policy, without the necessary evidence to guide effective implementation. EHRs were originally conceived as a means of decreasing medical errors, improving patient care, and increasing provider efficiency. The prevalence and astonishing impact of medical errors within the health care system received worldwide attention in 1999 when the Institute of Medicine published the groundbreaking study, *To Err is Human*, which found that "as many as 98,000 people die in any given year from medical errors that occur in hospitals."[56] The Obama administration recognized the promise of EHRs to address these high profile concerns in the American health care system and incorporated incentives for adoption of EHRs into the language of the American Reinvestment and Recovery Act (ARRA), in 2009.

[56] Kohn, Linda T, Janet M. Corrigan, Molla S. Davidson. *To Err is Human.* 2000.

However, implementation of the relatively new and unproven technology across the country remained inconsistent, and so additional policies were enacted in the 2015 Medicare Access and CHIP Reauthorization Act (MACRA) to accelerate the pace of implementation. However, without research and evidence to guide the effective implementation of EHRs in the clinical space, this accelerated adoption simply added complexity for already overloaded health care workers and increased regulatory requirements for documentation and compliance. In addition, competitive industry factors led to persistent problems with information blocking and a lack of interoperability by competing EHR vendors. All this has largely influenced the current health care landscape, where much of the blame for the epidemic of physician burnout and continuously increasing costs is placed on the very technology that was intended to be a solution to these concerns.

Case Study 2: Legislating in the Dark: When the Laboratories of Democracy are Run by Politicians in White Coats

When writing language employed for health care policy state officials must strike a careful balance between specificity and ambiguity. Language that is too specific has the potential to lead to both unintended restrictions and unanticipated loopholes to circumvent the policy. Language which is too vague can prove difficult to interpret and apply in specific scenarios, may weaken the impact of the policy, and may leave those advocating for the policy feeling as though it lacks the necessary teeth. A *policy follows* approach which incorporates available scientific evidence into health policy language

can be a key factor in informing that balance, and if scientific evidence is unavailable or insufficient, the resulting legislation can undermine the goals of the policy.

An illustrative example of this issue is found in the wide variety of state telehealth parity legislation and regulation around the country. Parity legislation and regulations serve to regulate payment from private and public insurers for the provision of telehealth services, just as they would for in-person health services. According to the Center for Connected Health Policy, forty-two states and the District of Columbia currently have legislation that governs private payer reimbursement of telehealth services, while all fifty states and the District of Columbia include some form of reimbursement regulation for telehealth services, through either private or public payers. Only ten states have passed total parity laws—in which all payers reimburse exactly the same amount for every service provided—regardless of the delivery modality. However, the language found in different parity laws across the country varies markedly, which can have a dramatic impact on the development of telehealth services in those states.[57] The term "parity" refers to the fact that early legislation was aimed at ensuring uniformly equal payment for telehealth services compared to similar services provided face-to-face. However, the language of current parity laws often diverges markedly from that early goal, at times creating restrictions to reimbursement or regulatory hurdles for telehealth services where none previously existed. Because of a lack of rigorous scientific data to guide state parity legislative language, variation across states compounded, as the expected impact of such legislation was based on the theories and opinions of the various

[57] Center for Connected Health Policy, Staff. *State Telehealth Laws and Reimbursement Policies Report.* 2020. https://www.cchpca.org/telehealth-policy/state-telehealth-laws-and-reimbursement-policies-report

stakeholders engaged in the policy development process in each state—rather than on evidence of actual impacts. This environment created a confusing milieu of regulations across the country, which was particularly problematic for a technology that was designed to allow doctors to reach patients regardless of their geographic location.

The COVID-19 pandemic has created a seismic shift in both state and federal telehealth coverage and payment legislation and regulations through waiver mechanisms and emergency declarations, but these changes are temporary, with many waived regulations reverting back to the pre-pandemic state, either at a specified date or once the emergency declaration has ended. As the nation was forced to shift dependence from in-person, traditional care, to care via remote technologies—policymakers, hospital systems, and clinicians alike—found themselves struggling to devise ways to provide the technology in the most efficient and practical ways. The policy and regulatory environment around telehealth was, by necessity, simplified and streamlined around the country.

As the health care system looks toward emerging from the pandemic response, the debate about how to continue to provide these services in a post-pandemic era and the variability across states in pre-pandemic policies, leads to questions that can only effectively be answered with a *policy follows* approach. Since telehealth policies prior to the pandemic were driven more by the concerns of private payers, for-profit companies, and powerful special interest groups, the data to guide new policies is largely lacking. Without research to inform the drafting of new, more consistent statutes regarding the use of technological advancements in care, we may find ourselves in more of a morass

than before, as the health care landscape has forever been altered by this pandemic. However, a shift in focus for health care IT policy to the advancement of research into best practices for telehealth and health IT will allow for not only more effective implementation, but more consistency across the country.

Case Study 3: The Cautionary Tale of Theranos: When Government Elites Embrace Alchemy

A balance between multiple stakeholders is crucial to the proper regulation and evolution of health care technology. When an appropriate balance between industry influence, policy makers, regulatory agencies, scientists, and clinicians is not maintained, failures can result. When regulations and policies are driven by hype rather than real evidence, those failures can be dramatic.

In 2003, nineteen-year-old Stanford University dropout, Elizabeth Holmes founded a Silicon Valley start-up called Theranos, which claimed it could deliver scientifically accurate results on a broad array of diagnostic tests using only the amount of blood provided by a finger-stick capillary sample. Holmes alleged that this technology, dubbed The Edison, held the potential to disrupt the health care sector, decreasing the system's reliance on painful and anxiety-provoking venous blood sampling from patients, delivering results in a matter of a few hours (versus the traditional span of several days), and decreasing the costs to Medicare and Medicaid by nearly half. These benefits, Holmes argued, would be multiplied substantially if consumers could order their own

laboratory tests independent of their health care provider, eliminating the cumbersome intermediary step of obtaining a physician order for lab tests—a step that was primarily serving as a barrier to efficiency and patient autonomy.[58] Holmes leveraged the considerable media attention she received to accrue nearly $700 million in venture capitalist financing, assemble a powerful and influential board of investors that included former Secretaries of Defense, Henry Kissinger and George Schulz, and then retired Four-Star Army General, James Mattis. Holmes was able to make lucrative deals in which she opened "Wellness Centers" in forty-two Walgreens located in Pennsylvania, California, and Arizona. In 2015 she successfully lobbied the Arizona legislature to pass a law allowing consumers to order any panel of tests they wished from the Theranos menu, without an order from their physician. This caught the attention of government officials who recognized the political appeal of consumer autonomy and potential cost-savings—and simultaneously—the ire of HMO and medical insurance companies who recognized the potential disruption of the insurance industry's traditional role as a gatekeeper for health care services. Prominent political powers of the time continued to take interest in both the positive press and money-making potential of the company, including the Clintons who invited her to speak at the Clinton Foundation Health Access Initiative forum and accepted her invitation to host a fund-raiser for then presidential-candidate Hilary Clinton. (Mrs. Clinton later cancelled the fund-raiser when stories of improper regulatory strategies began to circulate). In March of 2018, the Securities and Exchange Commission (SEC), filed a lawsuit against Holmes[59] and her former Chief

[58] Belluz, Julia. "The Theranos Contrversy, Explained." *Vox.* 2015.

[59] "Securities and Exchange Commision v. Elizabeth Holmes." 2018.

Operating Officer, Sunny Balwani, claiming that they had defrauded investors, businesses, and consumers, by misleading investors as to their accurate financial status, misleading businesses and the American government about the Edison's true capabilities and accuracy, and lying to investors about the regulatory status of their technology. The Department of Justice also filed suit against the two charging them with eleven criminal felony counts, in April of 2018.[60] Theranos is now defunct. Holmes settled her SEC case in early 2019 but Balwani's SEC case is still pending. Both Holmes and Balwani are awaiting their criminal trials.[61]

The story of Theranos is now cited as a cautionary tale for Silicon Valley start-ups, who are known to employ dubious strategies to avoid the hurdles associated with regulatory compliance. Jina Choi, lead counsel for the SEC in the case, was quoted as saying, "The Theranos story is an important lesson for Silicon Valley. Innovators who seek to revolutionize and disrupt an industry must tell investors the truth about what their technology can do today, not just what they hope it might do someday."[62] However, it is not only the technological industry that has been put on notice. There are warnings, too for regulatory agencies and state and federal policymakers. The current regulatory environment is steeped in the constraints of adversarial legalism. Intense pressures from Congress, the Executive Branch, and influential interest groups to not issue regulations which will dampen the economic contributions of the technology sector (both to the nation's GDP and to some of the political elite within its systems), frequently

[60] Johnson, Carolyn. "SEC Acusses Theranos of Elaborate Years Long Fraud." *The Washington Post*. 2018.
[61] Copeland, R. *"Elizabeth Holmes Gets Delay in Trial-Date Decision." The Wall Street Journal.* 2019.
[62] Bloomberg. "The Theranos fraud case has a lesson for start-ups: The SEC is watching for any missteps." *The Los Angeles Times*. 2019.

compete with the need to create regulations for the sake of consumer and patient safety. But this can often be further complicated when the evolution of the technology, or in the case of Theranos, the *perceived* evolution, outpaces the ability of governing agencies and officials to provide the due diligence required when writing effective rules.

CONCLUSION

How do we move forward safe and effective health IT policy? My thesis is that effective policy development must be guided by strong scientific evidence from rigorous research and knowledgeable experts. Such an evidence-based policy model facilitates greater precision in policy language and allows for more accurate prediction of the impact of policies on costs, access to care, and quality. The *policy follows* approach is particularly necessary and impactful when legislating health IT. The evolution of the U.S. health care system was initially driven effectively by advances in technology, but politics and industry stakeholders have become increasingly dominant forces over time, which has led to an expensive, inefficient, and stubbornly stagnant system. As described above, traditional economic models fail to fully address the complexity of this uniquely American health care environment. A *policy leads* model or approach, which attempts to apply traditional economic principals to health care by creating financial incentives or imposing penalties to encourage the adoption of technology, often creates as many problems as it solves.

The case studies described above detail the pitfalls of a *policy leads* approach. The rushed implementation of electronic health records into clinical practice shows that policies enacted to push adoption of unproven health care technology can have long-lasting negative consequences. The experience with variable state parity legislation for telehealth demonstrates that insufficient or inadequate research data can complicate policy development and lead to inconsistent, overly restrictive, or vague and confusing policy language. Finally, the cautionary tale of Theranos warns that media hype and pressure from powerful stakeholders can lead to policy and regulatory changes that put the safety of patients and the quality of health care at risk.

A *policy follows* approach would align policy makers, innovators, researchers, health care providers, and payers toward the same goals and facilitate a unified path for advancement of policy and regulation by: 1) developing technology that positively impacts the health of populations, the efficiency of the system, and the costs of care; 2) supporting research and data collection to prove that it works; and 3) developing policies and regulation to support the broad adoption of the proven technology. All stakeholders must recognize that, when dealing with health care policy and regulations, lives are truly at stake. A poorly informed or improperly vetted regulatory change can indeed put the safety of patients and the quality of health services provided at risk. This is perhaps the most critical reason why health care policies must *follow* research and evidence. Health care providers are trained from the earliest days of their career to follow evidence-based practice, and policy makers should follow their lead.

CHAPTER 3 – We Were not Prepared: The Lessons of COVID 19

INTRODUCTION

"Only a crisis—actual or perceived—produces real change. When that crisis occurs, the actions that are taken depend on the ideas that are lying around. That, I believe, is our basic function: to develop alternatives to existing policies, to keep them alive and available until the politically impossible becomes the politically inevitable." **- Milton Friedman**

Chapter 3 is dedicated to elucidating the pre-pandemic health care policy and regulatory environment—specifically as it relates to telehealth. While this thesis proposes the need for an alternative approach to health care technology policymaking from the broadest perspective, it was in the midst of this pandemic that telehealth emerged as the most urgent and timely innovation. It provides the perfect case for why the *policy follows* approach laid out in Chapters 1 and 2 offers the surest and most sensible guide for rebuilding our broken health care system in a well-informed and inclusive manner. This pandemic has provided the political will to re-set our collective perspective on what an efficient and equitable health care system should provide. And while the political agenda may not have shifted with it, the *policy follows* approach provides, finally, a way of tuning out the political noise. It provides a chance for bi-partisan recognition of a path forward toward the goal of attaining a truly value-based system.

The COVID-19 pandemic has put immense strain on the U.S. health care system and disrupted many of the traditional channels of delivering health care. Due to the risks of COVID-19 exposure to patients, families, providers, and health care facility staff from delivery of in-person care, practitioners across the country, and the world, has shifted services rapidly toward telehealth and other virtual and remote care services. According to a McKinsey and Company report, [63]more than 70% of in-person health care visits were cancelled at the outset of the pandemic. In their place, telehealth visits were scaled rapidly and dramatically, with health care providers of all types reporting that telehealth visits increased 50 to 175-fold. Whereas in 2019 only 11% of consumers had used telehealth, during the pandemic 76% of those surveyed indicated that they were highly or moderately likely to use telehealth services in the future.

What makes this incredible surge in telehealth usage during the pandemic even more remarkable is that in the five to ten years prior to the pandemic, much of the debate about telehealth policy and payment was focused on the lack of expected progress with adoption and integration of services. Despite the relatively straightforward technological approach and the obvious theoretical benefits, adoption of telehealth services across the health care system had, for years, been stuck somewhere between 10-15% for both patients and providers[64]. But almost, overnight, health care institutions across the country scaled telehealth across entire enterprises.

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[63]Oleg Bestsennyy, et al. "Telehealth: A quarter-trillion-dollar post-COVID-19 reality?" *McKinsey & Company*. May 29, 2020. https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality

[64] Blake Sisk, Joshua Alexander, Chelsea Bodnar, et. al. "Pediatrician Attitudes Toward and Experiences With Telehealth Use: Results From a National Survey". *Academic Pediatrics*. May 8, 2020. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7207114/

It is rare that the political, social, technological, and environmental factors driving the adoption of a health care technology change so rapidly and dramatically. Such a spectacular shift creates a unique opportunity to evaluate the many factors that created a relatively stagnant environment around telehealth—pre-pandemic—but also has created such a seismic shift during it, and which will shape the response of the health care system in its aftermath. Thus, this chapter will focus on telehealth during and after the pandemic as an ideal laboratory for the evaluation and application of the *policy leads* versus *policy follows* approach to health care technology policy.

THE PRE-PANDEMIC POLICY PREDICAMENT

Prior to the pandemic, the expansion of telehealth was subject to the complexities of the U.S. health care system as discussed in Chapters 1 and 2. A largely fee-for-service payment system put various stakeholders at odds regarding the best path forward. Employing the technology to reduce hospital or Intensive Care Unit (ICU) admissions, as many programs had been shown to do[65], certainly benefitted the patient and the payer, but might have decreased revenue for hospitals[66]. Programs that provided convenient access to urgent care services for minor conditions such as sinusitis or a sore throat, were convenient for patients but increased overutilization and increased expense for payers and put community health care providers at risk by decreasing utilization of their practices.

[65]Jillian Harvey, et al. "The Impact of Telemedicine on Pediatric Critical Care Triage." *Pediatric Critical Care Medicine.* November 18, 2017. https://pubmed.ncbi.nlm.nih.gov/28922271/
[66]Byung-Kwang Yoo, et al. "Economic Evaluation of Telemedicine for Patients in ICUs." *Critical Care Medicine.* February 2016. https://pubmed.ncbi.nlm.nih.gov/26540398/

Low utilization of telehealth services became a chicken or egg scenario, as the investment of time and resources required to integrate telehealth workflows into electronic health records (EHRs), scheduling, and billing practices led to telehealth services using stand-alone mini-EHRs and often billing patients out-of-pocket rather than billing insurance. This complicated the collection of consistent data about the services provided, since much of that data is collected via EHRs and payer claims data. Without the necessary evidence from well-collected, consistent data supporting the benefit of the services, providers were slow to adopt telehealth, and payers and policymakers were reluctant to reimburse for the services.

The lack of consistent reimbursement for services and poor integration with EHRs led to a focus on relatively simple-to-implement services. This concentrated telehealth development on minor, acute patient complaints for which patients often sought convenient care and would be willing to pay a small amount out of pocket. The effective management of chronic and complex conditions requires coordinated care teams, often with multiple specialties, easy access to patients' historical medical records, and well-established follow-up mechanisms. Therefore, telehealth services supporting more coordinated care approaches were largely confined to academic institutions which had grant funding allowing them to pursue development of such programs.

Because non-grant-funded telehealth providers were racing to develop and roll-out new services, resources were very often devoted to those development efforts, but generally not devoted to data collection, quality improvement, and research activities[67]. And thus,

[67] Christina Olson, et. al. "The Current Pediatric Telehealth Landscape". *Pediatrics.* March 14, 2018. https://pubmed.ncbi.nlm.nih.gov/29487164/

the problem continued to compound itself, as the lack of reliable data inhibited adoption across the care system, and the lack of adoption in turn prevented the collection and evaluation of adequate data to produce meaningful results.

Additionally, because the target demographic for urgent care type programs aiming to treat minor, acute conditions was patients who could afford to pay out of pocket and had easy access to technology, populations without those resources—the poor, rural, or otherwise underserved—were often overlooked. This included non-English-speaking populations, for whom telehealth platforms generally did not have integrated interpreter services or multi-lingual interfaces.

Finally, the state-to-state variation in payment for telehealth services, licensure requirements, malpractice coverage, privacy regulations, and more led to a mire of regulatory and policy variations that made practicing telehealth across state lines a significant undertaking. Clear policy and regulatory guidance for a given state was often difficult to come by, and an understanding of the policy and regulatory environment in multiple states was a true rarity. These complications, combined with the technological investment and expertise required for startup and maintenance of most telehealth services prevented the majority of smaller practices from making the leap into provision of remote care, leaving the development of telehealth to larger institutions with the resources and proficiency to support such efforts.

NECESSITY IS THE MOTHER OF ACCEPTANCE

A generally accepted premise of political theory is that political forces that are already in motion, however slowly moving, are always accelerated during times of crisis, such as economic calamity, war, and plague. Without the Great Depression, we would not have macro-economic policy, nor would we have realigned our political parties. Without World II there would be no UN, WHO, WTO, nor other acronyms of global collaboration. The COVID-19 pandemic has battered the U.S. with two of these three crises in a very short span of time. The factors influencing the historical development and current state of the U.S. health care system, which were detailed in Chapter 1—the lack of a single payer system, largely fee-for-service payment models, and the rise of employer-based health insurance—all contributed significantly to the extraordinary pressures placed on health care providers across the country at the onset of the pandemic.

Hospitals, health systems, and individual practices all saw patient volumes and revenue fall precipitously. Even emergency rooms outside of "hot zones," which all braced for a surge of COVID-19 patients, saw overall volumes drop dramatically, as patients have avoided ERs and clinics for fear of infection[68]. Elective surgeries have been cancelled or delayed, as have scheduled ambulatory visits. Health systems across the country have placed many staff on temporary or permanent furlough to cut costs. In a value-based health care system, such reductions in volume would not create significant financial strain. However, in a fee-for-service model they threatened the financial viability—and in

[68] Benjamin Wessler, David M. Kent, Marvin A. Konstam. "Fear of Coronavirus Disease 2019—An Emerging Cardiac Risk". *Journal of the American Medical Association.* July 22, 2020. https://jamanetwork.com/journals/jamacardiology/fullarticle/2768742

some cases, even the actual existence—of many institutions.[69] [70] Third-party health insurance plans, on the other hand, have made a fortune.[71] While some discounted premiums for beneficiaries, the majority adopted the position that financial windfalls early in the pandemic resulting from decreased utilization would be completely offset in future months by a surge of either COVID-19 related utilization, or heavy utilization due to "catch up" visits and care for chronic conditions that have worsened during the pandemic due to inadequate attention. Federal and state governments have stepped in with stimulus funding to support at-risk health care facilities, which added to the costs associated with the already monumental economic crisis.[72] Countries with a national health care system, by contrast, have avoided such strains and imbalance, since decreased utilization of services also decreased their own costs.[73] Finally, given the United States' employer-based insurance system, as unemployment soared the number of uninsured across the country has risen precipitously as well, creating further, short and long-term, challenges for access to care.[74]

Adding to these financial burdens, health care providers find themselves facing new and unforeseen challenges to the delivery of care. While health care system capacity in

[69] April Simpson. "Rural Hospitals Hang on as Pandemic Reaches Smaller Communities". *Pew Trusts.* July 22, 2020. https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2020/07/22/rural-hospitals-hang-on-as-pandemic-reaches-smaller-communities
[70] "Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19". *American Hospital Association.* May 2020. https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due
[71] Reed Abelson. "Major U.S. Health Insurers Report Big Profits, Benefiting From the Pandemic". *The New York Times.* August 5, 2020. https://www.nytimes.com/2020/08/05/health/covid-insurance-profits.html

[72] ASPA. "CARES Act Provider Relief Fund: General Information". *Health and Human Services.* March 24, 2020. https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html
[73] Lindsay Maizland and Claire Felter. "Comparing Six Health-Care Systems in a Pandemic". *Council on Foreign Relations.* April 15, 2020. https://www.cfr.org/backgrounder/comparing-six-health-care-systems-pandemic
[74] Rachel Garfield et al. "Eligibility for ACA Health Coverage Following Job Loss". *Kaiser Family Foundation.* May 13, 2020. https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/

some areas, particularly ICU capacity, has been overwhelmed, other facilities outside of hot zones sit with entire floors empty. Even those facilities, however, have faced critical shortages of personal protective equipment (PPE). Many practitioners and support staff themselves are often at high risk of COVID-19 related morbidity and mortality due to age or pre-existing conditions such as hypertension, diabetes, or immune suppression from any cause. Even those who are young and healthy risk transmission of the virus to sick or at-risk loved ones or friends outside work. In-person school was cancelled across the country, putting additional strain on health care workers with school-aged children. Families and friends have been restricted from visiting loved ones in the hospital. COVID-19 testing resources have been limited and in high demand, but the infrastructure to provide testing in a safe and effective manner was initially non-existent.[75]

A *Nearly* Ideal Solution: Ten Years of Change in Three Weeks

Within this unprecedented environment, telehealth and virtual care approaches have been ideally suited to address many of the challenges arising from the pandemic. Remotely caring for patients has allowed for physical distancing and accordingly protects patients, families, providers, and staff. Telehealth capabilities have allowed conservation of precious PPE and closer monitoring of patients outside of an ICU setting. Remote patient monitoring approaches also have allowed low-risk patients to be managed at home. Direct-to-consumer telehealth platforms previously intended to care

[75] Preeti Mehrotra, Preeti Malani, Prashant Yadav. "Personal Protective Equipment Shortages During COVID-19—Supply Chain-Related Causes and Mitigation Strategies". *JAMA.* May 12, 2020. https://jamanetwork.com/channels/health-forum/fullarticle/2766118

for minor, acute conditions have been quickly repurposed as virtual triage platforms. This has allowed patients who have been concerned that they might require a COVID-19 test to complete online assessments screens and then be cleared for access to rapidly erected drive-through testing facilities. Families restricted from visiting ill loved ones can visit via videoconference. Perhaps most critical to the viability of the health care system, virtual care has allowed providers to continue to care for their patients and maintain a stream of revenue, and continuity with their patients, even when in-person visits have been nearly non-existent. Ambulatory services have shifted toward virtual care in a matter of days. Telehealth seemed like the solution to nearly every problem the pandemic has posed.

But we were not prepared. The pre-pandemic telehealth environment, as outlined above, was largely geared toward management of minor, acute conditions with out-of-pocket payment models that often didn't require standard billing and documentation. Therefore, integration of telehealth services into standardized workflows of the electronic health record (EHR)—for scheduling, intake, documentation, billing, etc.—was limited. Additional programs that provided virtual emergency room care, such as telestroke services, were not heavily utilized because patients were not presenting to emergency rooms. Services had been targeted toward "consumers" with easy access to technology and the means to pay out of pocket, so adequate technology and processes needed to ensure access for underserved, rural, and disadvantaged populations were not in place. Furthermore, the patients at highest risk for COVID-19 morbidity and mortality—racial minorities, non-English-speaking populations, the chronically-ill—often had limited access to telehealth options since services had not been designed with

them in mind. Further complicating the rapid roll-out of telehealth services was the fact that due to the low pre-pandemic adoption of telehealth practice across the health care system, the vast majority of providers who were suddenly tasked with treating patients remotely had minimal to no training or experience with provision of virtual care. Subsequently, the vicious cycle summarized above—low adoption by clinicians, leading to insufficient evidence to support telehealth utilization, in turn leading to inadequate payment for telehealth—all of which contributed to low clinician adoption, was once again salient.

Further adding to the burdens, strains, and anxieties described above was the urgent requirement for health care Information Technology (IT) teams to abruptly design new technical systems, redesign workflows, implement new technical support processes, revamp billing and documentation procedures, and deploy or repurpose enormous amounts of equipment—across vast health systems—in only a matter of days.

From a government perspective, this new landscape and myriad challenges meant that the existing state-to-state variation in telehealth policy and regulation presented insurmountable barriers on a critically short time frame. HIPAA provisions which restricted the platforms that could be used for virtual services, and federal payment policies that restricted provision of care via telehealth into patients' homes, outside of rural areas, or by limited types of providers, would have made the solutions afforded by telehealth untenable. State and federal policymakers responded out of necessity, dropping restrictions and opening up payment for telehealth.[76] Accordingly, the

[76] ASPA. "Telehealth: Delivering Care Safely During COVID-19". *Health and Human Services.* July 15, 2020.

explosion of telehealth across the country during the pandemic has not been triggered by policy changes, but rather, the explosion of telehealth has been the trigger for policy and regulatory change. *Policies have followed* the clearly identified needs of the health care system.

The Government Response: COVID-19 Legislative and Regulatory Changes

The federal response to the COVID-19 pandemic has been extensive and has highlighted some of the difficulties posed by a federated system to an adequate public health emergency response. On January 31, 2020, Alex Azar, the U.S. Secretary for Health and Human Services (HHS) issued a public emergency under the Public Health Service Act (PHSA)[77]. This issuance was intended to release funding and facilitation for precipitous development of rapid diagnostic tests, assessing the effectiveness of established drugs or the development of new antiviral treatments and vaccines. On March 13, 2020, President Trump used the National Emergencies Act to declare a National Emergency, which allowed for waiver of current federal rules to enable broad and rapid use of existing telehealth technologies and increase hospital capacities. Additionally, Trump declared an emergency under the Stafford Disaster Relief and Emergency Assistance Act, proclaiming "the preeminent responsibility of the Federal Government to take action to stem a nationwide pandemic."[78] This allowed for a number of powers—not all of which are relevant to this thesis—to be exercised. However, it is important to note that the complicated interplay between the powers these national emergency statutes permit our federal and state governments and what latitudes they

[77] Public Health Service Act. 42 USC 264(a) (2018).
[78] Robert T. Stafford Disaster Relief and Emergency Assistance Act. 42 USC 519(b) (2018).

allow our national health agencies to deploy under certain conditions, is antiquated. They had not, at the time of these declarations, been truly tested.[79] This pandemic has exposed numerous vulnerabilities in our ability to leverage the cutting edge health care technologies the U.S. has developed while balancing them with the infringement of certain constitutionally guaranteed individual freedoms, the difficulties of uniform enforcement of national health agency guidelines, and the challenges of the prevailing political zeitgeist.

Telehealth Specific Emergency Waivers

Waivers impacting the provision of telehealth—and closely interrelated health technology practices—implemented as a result of emergency declarations, legislation, and regulatory changes, fell into four main categories: alterations to Medicare, alterations to state Medicaid and private payer guidelines, licensure requirements, and regulatory enforcement of HIPAA.

The Coronavirus Aid, Relief, and Economic Securities (CARES) Act was passed and signed into law on March 27th, 2020.[80] CARES included $45 million for the Federal Emergency Management Agency (FEMA) to expand information technology, build communication capacities, and increase the capacity in response to these coordinated efforts. Nine million was allotted to the Cybersecurity and Infrastructure Security Agency

[79] Lawrence Gostin, James G. Hodge, Lindsay F. Wiley. "Presidential Powers and Response to COVID-19". *JAMA.* March 18, 2020. https://jamanetwork.com/journals/jama/fullarticle/2763423

[80] "The CARES Act Works for ALL*".* The US Department of the Treasury. March 2020. https://home.treasury.gov/policy-issues/cares#:~:text=The%20Coronavirus%20Aid%2C%20Relief%2C%20and,Trump%20on%20March%2027th%2C%202020.

(CISA) to develop or improve supply chain and information analysis and to implement critical infrastructure coordination. Of the $140.4 billion provided to HHS, $275 million was specifically earmarked for expansion of care to rural hospitals, poison control centers, and the Ryan White HIV/AIDS program, utilizing telehealth, through the Health Resources and Services Administration (HRSA). Five hundred million was designated for investment in public health data surveillance and infrastructure modernization (a program which had been initiated just prior to COVID), to assist states with developing COVID-19 tracking and reporting tools. In addition, funding was provided to the Veteran's Administration to expand capacity of its IT networks, to broaden telehealth capabilities and address the increased demand for virtual services. Finally, the Secretary of HHS was directed to consider ways to encourage the use of telecommunications systems, including for remote patient monitoring and other communications or monitoring services, clarifying guidance, and conducting outreach to state governments.[81]

As mentioned in an earlier section of this chapter, state-to-state variations in licensing requirements had created barriers to addressing shortages in the number of available health care providers. The CARES Act allowed states to waive in-state licensing requirements for providers delivering telehealth, per specific terms and conditions. But these "specific terms and conditions" were left to the states to determine. Florida became an early, notable example as it approved out-of-state providers to deliver services through telehealth to Floridians without attaining a license for the duration of

[81] "COVID-19 Stimulus Bill: What It Means for States". *National Council of States and Legislatures.* April 2, 2020. https://www.ncsl.org/ncsl-in-dc/publications-and-resources/coronavirus-stimulus-bill-states.aspx

the public health emergency. By March 26, 2020, twenty-six states had waived licensure. As of October 16, forty-two states and three U.S. territories had modified requirements for licensing.[82]

One of the more complicated changes enacted by CARES is the latitude given to states to expand telehealth coverage via Medicaid. In general, the Act provided that states could amend existing Medicaid rules to include one or more of the following:

- loosening the limitations on payment based on the location of the patient
- requiring that provider reimbursement for via telehealth be the same as that of a traditional in-person visit
- expanding coverage of certain service via telehealth (examples include mental health, dentistry, physical therapy, occupational therapy, outpatient respiratory therapy, etc.)
- allowing for multiple methods of telehealth (such as telephone visits without the requirement of video)
- removing the requirement of an initial face-to-face appointment to establish a provider relationship

As of June 2020, all fifty states had undertaken some type of action to expand Medicaid coverage to assist in caring for COVID-19 patients.[83]

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[82]U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19". Federation of State Medical Boards. Last updated October 16, 2020. https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf

[83] Madeline Guth and Elizabeth Hinton. "State Efforts to Expand Medicaid Coverage & Access to Telehealth in Response to COVID-19". *The Kaiser Family Foundation.* June 22, 2020. https://www.kff.org/coronavirus-covid-19/issue-brief/state-efforts-to-expand-medicaid-coverage-access-to-telehealth-in-response-to-covid-19/

While the CARES Act loosened restrictions on federally funded programs' provision of telehealth, they could not mandate changes to commercial or private health care insurance providers. This allowed private insurance payers to negotiate with individual states regarding what expansions should be made for telehealth coverage. As of passage of the CARES Act, seventeen states had mandated that commercial insurance carriers cover telehealth throughout the duration of the declared public emergency. However, what exactly "coverage" meant was a matter of concession between the state and the payer. Negotiated expansions included a wide variety of modifications including, but not limited to, waiving all co-pays, coinsurance, and deductibles for patients whose care related to COVID-19 diagnostic testing and requiring provider reimbursement for telehealth be the same as reimbursement for an in-person visit. Private insurers are now beginning to re-evaluate payment approaches for telehealth as the volume of in-person visits begins to normalize.

Much like the morass of state and federal laws concerning the provision and coverage of telehealth, the confusing mix of state and federal laws regarding HIPAA privacy regulations also presented challenges to providing effective care and rapid communication of disease status to community and federal health agencies. In response, the Office of Civil Rights (OCR), which is charged with enforcement of HIPAA regulations, announced that it would not impose penalties for non-compliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth for the duration of the emergency. Importantly, this allowed the use of certain non-public facing, non-HIPAA

compliant communications platforms, such as FaceTime and Zoom, to be used for telehealth visits.[84] This flexibility was critical to the timely ability of many practices, particularly smaller practices, to communicate via video with their patients if they had not previously invested in implementing a HIPAA-compliant solution.

A CLEAR PATH FORWARD – IF WE CAN ALL AGREE TO SEE IT

The pandemic will require that we rebuild our health care system. We cannot return to provision of care as before because the twin crises of economic calamity and plague have exposed the weaknesses of our fee-for-service, employer-based system. But, of more consequence, it has created a new reality in which these, and other, fundamentally flawed systems can no longer continue to function effectively. We find ourselves in a completely altered landscape from where things stood less than a year ago. The solutions needed to integrate health care technology, such as telehealth, into the care system are now tightly intertwined with the required evolution of the health care system itself. There is a pressing need to accelerate the shift to value-based payment models, create a more stable financial environment for health care providers, address the obvious racial and ethnic disparities in the system, and develop a more robust and adaptable public health program.[85]

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[84]"Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency". *U.S. Department of Health and Human Services*. March 30, 2020. https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

[85] David Blumenthal, Elizabeth J. Fowler, Melinda Abrams, Srara Collins. "Covid-19—Implications for the Health Care System". *The New England Journal of Medicine.* October 8, 2020. https://www.nejm.org/doi/full/10.1056/nejmsb2021088

The shift to value-based care and creation of a more resilient financial structure for health care providers go hand-in-hand. Even before the pandemic, poorly compensated services like primary care and mental health, and safety net hospitals in poor and underserved areas were struggling to survive, while more expensive services were encouraged under the current fee-for-service system. And health systems often relied on those more expensive, high volume services to offset the cost of providing the lower paid services. This pandemic cleaved those symbiotic relationships, causing already vulnerable services to falter even more and overtaxing some systems' ability to keep pace with the demand for acute, specialized care. The pandemic starkly exposed the susceptibility of our current payment system to any major fluctuation in the market. If well paid services are no longer in demand, the system collapses and health workers, ironically already in too short a supply to provide for all of our citizen's health care needs, lose their jobs.

The integration of virtual care options into a hybrid model of care could provide health care practitioners and systems with the adaptability and resiliency so desperately needed in the face of turbulent times. The health system's response to the pandemic was to support the care givers who normally provide in-person services by adding the provision of virtual care, and as in-person visits have regained momentum, those providers have likewise transitioned away from telehealth. However, it should be realized that maintaining the flexibility of clinicians to provide services via either in-person or virtual care, depending on the circumstances and needs of the patient, will be important for several reasons. The evidence and experience from the pandemic shows that maintaining such a system will have multiple positive impacts: 1) it allows for the

flexibility necessary for health care providers to maintain continuity of care and revenue, regardless of the environment, 2) it encourages the integration of virtual care services into EHRs, improving data collection, documentation, and billing practices, 3) it supports primary care practices' participation in the provision of virtual care, and 4) it facilitates the management of chronic and complex disease through virtual care, versus only simple management of minor, acute conditions.

Key questions remain, however, that will need to be addressed through research and evidence. As the costs to payers of providing in-person services move back toward the more expensive pre-pandemic levels, they are wary of the potential for fraud, abuse, and overutilization of telehealth without a true understanding of the value it brings. And, the clinical impacts of virtual care at the population health level, particularly for chronic and complex disease, remains unclear.

Here is where the *policy follows* approach dictates that we focus resources and efforts in support of research. It is reasonable to expect that the development of a hybrid, flexible model of integrated, virtual, and in-person care options, provided by established physicians and specialists, would reduce the risk of fraud, abuse, and overutilization through better coordination and care planning. It is also reasonable to hypothesize that provision of virtual care into the homes of patients with medically complex and chronic conditions would result in better outcomes and lower costs. Fortunately, the incredible expansion of telehealth during the pandemic has generated a substantial trove of data around just such models of care. A focused effort on clinical and translational research

using this data to generate robust evidence to support, or refute, these ideas would provide a much clearer path forward for telehealth policy and regulation.

It must also be addressed that the statistics on the disproportionate effects of COVID-19 on Black and Hispanic persons is startling. According to a recent New England Journal of Medicine article, nearly 20% of the counties in the U.S. are disproportionately black, and these communities have accounted for more than half of the COVID cases and almost 60% of the COVID deaths, nationally.[86] The trend is not much improved for Hispanics. There are many deep, systemic causes for these findings but fundamentally, people of color and lower socio-economic status, have less access to coverage and care, leaving them more vulnerable to chronic illness. This population also tends to have food and housing insecurities which are often associated with lack of access to reliable transportation or internet. Research during the pandemic has already demonstrated that the surge in virtual care utilization may have exacerbated, rather than improved, disparities in access to health care. Investigators at the University of California – San Francisco demonstrated that, following the rapid scaling up of telemedicine visits at their two large primary care practices, a significantly smaller proportion of visits were with vulnerable patient populations (age 65+, non-English language preference, Medicare, and Medicaid patients) and minorities.[87] The authors proposed four key actions for clinicians and health system leaders "to ensure that the current telemedicine implementation does not exacerbate health disparities:… (1)

[86]David Blumenthal. "Covid-19—"Implications for the Health Care System." *New England Journal of Medicine.* October 8, 2020. https://www.nejm.org/doi/full/10.1056/nejmsb2021088
[87]Sarah Nouri, et. al. "Addressing Equity in Telemedicine for Chronic Disease Management During the Covid-19 Pandemic." *The New England Journal of Medicine.* May 4, 2020.

proactively explore potential disparities in telemedicine access, (2) develop solutions to mitigate barriers to digital literacy and the resources needed for engagement in video visits, (3) remove health-system created barriers to accessing video visits, and (4) advocate for policies and infrastructure that facilitate equitable telemedicine access." These steps align perfectly with a *policy follows* approach to developing telehealth legislation addressing disparities in access. The authors add, "Without taking these actions now, health care systems risk creating telemedicine programs that exclude vulnerable populations… We strongly recommend all clinicians advocate for changes at local, state, and federal policy levels."

"The ideas lying around": Federal Preemption

This brings us to perhaps the most critical, and likely most contentious, recommendation of the thesis: health technology policies established at the federal level should be preemptive of state legislation. As has been illustrated throughout these chapters, the state-by-state variation in policy, regulation, payment, and practice of telehealth has created monumental barriers to the effective development and adoption of telehealth services. The elimination of much of this variability has been vitally important to the use of telehealth to effectively respond to the COVID-19 pandemic. It is very likely that the most imminent threat is the resurgence of that state-by-state variability in policy, regulation, payment, and practice when the state of emergency ends or abates.

This state variation does not pose the same burden to the in-person practice of medicine because, by definition, the patient and provider are in the same location. In contrast, for a technology in which, by definition, the patient and provider are in different locations, such variation can be a monumental barrier to progress in many areas, including administration, billing, compliance, research, policy development, and the sharing of best practices.

Federal laws and regulations are already functionally, if not technically, preemptive in many spheres of health IT. Federal Medicare regulations pertaining to EHRs, for example, are functionally preemptive because the vast majority of EHRs cover Medicare patients, and the vast majority of providers care for Medicare patients, as at least some percentage of the population that they serve. Therefore, the design and operation of EHR functionality must conform to federal regulations to avoid the crippling complexity that would come from applying different regulations to different populations managed through the same system. Similarly, much of the health care technology developed for use in the U.S. adheres to federal regulations, since the target market is uniformly broader than a single state.

Because telehealth is more about how medicine is practiced for a population of patients than about the particular technology, however, federal regulations pertaining to a specific population, such as Medicare patients, can reasonably be applied only to that population, leaving other populations subject to rampant state variation. Federal preemption would provide stability, clarity, and cohesion for the practice of telehealth throughout the U.S. With the available data from the explosion of telehealth during the

pandemic, research is underway that could inform such federal policy using a *policy follows* approach, thus addressing the potential uncertainty and subjectivity around the development of federally-preemptive policy. One of the great benefits of quality science is that its findings don't change when you cross state lines, and therefore federal policy guided by science can reasonably be applied broadly as well. Federal preemption would greatly simplify the practice of telehealth, the adoption of best practices, and very importantly—particularly if guided by a *policy follows* approach—the design and conduct of impactful multicenter clinical, translational, health services, and economic research that would guide such policies.

The questions for researchers, which are highlighted by the pandemic and which should directly inform upcoming policy changes include:

- What is the true impact of the broad adoption of telehealth services on access to care for vulnerable populations?
- How does an integrated model of telehealth and in-person care impact the costs to health care providers, payers, and the system as a whole, in both a fee-for-service and value-based care model?
- What factors are most critical to the successful integration of telehealth and virtual care services through EHRs to facilitate efficiency of practice, at scale?
- How can telehealth services most effectively integrate multi-lingual support into services and platforms to support access to services by non-English speaking populations?

- How do technology barriers faced by rural, underserved, minority, and underprivileged populations impact their ability to access telehealth and virtual care services?

By focusing on these questions, and utilizing the data generated during the pandemic, research can not only improve the care provided within our health system, it can drive the development of meaningful and impactful health care technology policies that will positively shape our health care system for decades to come.

CONCLUSION: WHEN "THE POLITICALLY IMPOSSIBLE BECOMES THE POLITICALLY INEVITABLE"

We come back to where we started. Health technology must drive the evolution of the health care system now, just as it did with the rise of hospital care in the early 1900s and throughout our history. Thus, the guiding principles for health care technology policy must work synergistically with those for the health care system as a whole. Moving forward, policy development for health technology, should follow three core principles: 1) we should utilize *policy follows*, research, and expertise, 2) federal policies should, as a general rule, be preemptive of state policies for health technology, particularly telehealth, and 3) we must aggressively pursue value-based care models and move away from fee-for-service payment. These three core principles are each dependent on the other—like the three legs of a stool.

This presents an opportunity which has never before existed. The pandemic has made the politically impossible, the politically inevitable. The question now is how we make the inevitable a reality. The paradigm shift associated with the pandemic provides an extraordinary opening to alter the emphasis of the industry—and the research associated with it—to concentrate on areas that can provide the greatest impact to the health care system and the widest variety of patients. And perhaps most profoundly, it provides the ability to re-set the political agenda, which will finally allow for transition to a value-based model.

The proficiency most needed now is not industry or technical expertise. It is clinical and research expertise. We must follow the scientific process and base changes on clinical and translational research findings. The cautionary tale of Theranos should remind us that relying on the wrong expertise, and on an inappropriate political agenda, will lead us astray. In that case, policymakers banked on the expertise of industry leaders, and powerful political voices and their agendas, without the scientific evidence to back it up.

We cannot continue to make such mistakes. A *policy follows* approach dictates that we follow where the science leads. It also dictates that the researchers themselves are likewise guided. We must direct research questions toward the policy issues that are most in need of answers; we must also consider where research to answer those questions is still lacking. The coordination between researchers and policymakers must become more intentional and bidirectional. It is through such bidirectional communication that we will foster the most efficacious and politically expedient path to

the efficient, effective, inclusive, and innovative health care system our nation so desperately requires and deserves.

Conclusion

For a considerable period of U.S. history we have been wrestling with scientific innovations in health care, developing the best practices for providing the highest quality care possible, and subjecting those best practices to our complicated system of shifting political agendas, differing political and economic theories, and our government's complicated and unique system of checks and balances. The current state of our national health care system indicates the poor results of these intersecting—and often competing—efforts.

The United States has the world's most expensive health care system, and pre-pandemic, the percentage of our GDP it represented was consistently growing by astounding margins. How to fix such a broken system has become one of the major political pain points of our nation's ability to maintain a healthy citizenry. Bearing the onus of attempting to address the improvement of such a colossally complicated system and emotionally charged debate has become such perilous territory for politicians that few choose to do more than pay lip service to the need for change. In truth, the patchworked system we have created has become so ensnared in special interests, entrenched systems of care provision, and identity politics, that even those administrations who have possessed the ethos, courage, and intellectual capabilities to actually produce meaningful change, have seen their efforts and accomplishments dashed by those who cannot grasp the magnitude of the importance of fundamentally altering our approach to provide our citizens a robust, efficient, and equitable system of health care. The COVID-19 pandemic has dramatically highlighted these failures and

provided a crucial opportunity to re-imagine and implement the radical changes required. Sound evidence is required for both.

This thesis examines the crucible of historical, political, and economic factors which yielded the pre-pandemic system. Further, it examines specific cases to shine a critical light on the ways in which the system has failed. Most importantly, this thesis provides a new theory for approaching the task of transitioning toward a Value Based Care model and creating effective and forward-thinking health innovation policy in light of what we have learned—and will continue to learn—during the pandemic.

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